

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/549,799
Applicant : Dieter HERMANN et al.
Filed : September 19, 2005
TC/A.U. : 1623
Examiner : Crane, Lawrence E.

Docket No. : 2970-125
Customer No. : 6449
Confirmation No. : 7706

DECLARATION

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Brigitte HECKL-ÖSTREICHER, declare as follows.

1. I am one of the listed coinventors of the above-referenced U.S. patent application.
2. I am familiar with the subject patent application, including the currently pending claims. I am also familiar with the Office Action mailed May 21, 2007. I understand that claim 1 currently pending is directed to a nucleotide derivative. I understand that claim 8 currently pending is directed to a pharmaceutical composition of a nucleotide derivative and a pharmaceutically acceptable adjuvant or vehicle. I understand that claims 9 and 10 currently pending are directed to a method for treating malignant tumors by administering said pharmaceutical composition. I understand that claim 11 currently pending is directed to a method for treating malignant tumors by

administering said pharmaceutical composition in combination with other anticancer agents.

3. In my opinion, practicing the full scope of the invention is possible without undue experimentation. Specifically, the specification has enabled one of skill in the art to treat any of the enumerated neoplastic conditions, either with the pharmaceutical composition alone or in combination with an additional anticancer agent.

4. Data from additional examples 8 through 12 is attached and demonstrates that a pharmaceutical composition containing the nucleotide derivative can be used to treat breast, prostate, ovarian, pancreatic and cervical tumors, respectively. The results in examples 8 through 12 were obtained under conditions similar to those used in the colon cancer example provided in the specification. For example, the range of doses used in all the experiments is similar, the controls are similar and the dosing schedule is similar. Thus it is shown that, with the teaching of the application, one of skill in the art can treat not only the exemplified colon tumor, but all of a tested series of common other tumors.

5. The nucleotide derivative, as defined in claim 1, has a core structure which is completely defined, and a phosphoric acid ester group with a disubstituted glycerol. The substituents on the glycerol group have only a minor influence on the function of the nucleotide derivative and the substituents may not even be present at all. Thus, little experimentation would be required to determine the parameters of the full scope of compounds represented in the present claims.

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6. The treatment with several different drugs is common practice in tumor therapy. It is known in the art to combine anti-cancer agents and it is clear that any known anticancer agent can be used. Thus, the skilled artisan would be able to choose a substance which would fulfill the claim conditions.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

B. Heckl-Östreicher
Brigitte HECKL-ÖSTREICHER

20.08.2007
Date